room light and using a high-intensity monodirectional light beam. In addition, turbidity and particle content were measured electronically. Chemical stability of the drug was evaluated by using a stability-indicating high performance liquid chromatographic (HPLC) analytical technique.

All samples were physically compatible throughout the study. The solutions remained clear, and little or no change in particulate burden and haze level were found. Additionally, little or no loss of palonosetron HCl and dexamethasone occurred in any of the samples at either temperature throughout the entire study period.

Example 8

Formulation III

The following is a representative pharmaceutical formulation and container closure for palonosetron that is useful for intravenous infusion formulations.

Ingredient	Amount (mg)
Palonosetron Hydrochloride	0.75[a)]
Sodium Chloride	450.0
EDTA	2.5
Sodium citrate	18.5
Citric acid monohydrate	7.8
WFJ	q.s. to 50 mL
Sodium hydroxide solution and/or hydrochloric acid solution	pH 4.8 ± 0.5
Container closure system	plastic container[b)] plus rubber stopper[c)]

[a)]Calculated based on the weight of free base
[b)]Polyethylene multilayer film infusion bag.
[c)]Isoprene rubber stopper.

This invention has been described with reference to its preferred embodiments. Variations and modifications of the invention will be obvious to those skilled in the art from the foregoing detailed description of the invention.

What is claimed is:

1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol,

wherein said formulation is stable at 24 months when stored at room temperature.

2. The pharmaceutical formulation of claim **1**, wherein said EDTA is in an amount of 0.5 mg/mL.

3. The pharmaceutical formulation of claim **1**, wherein said mannitol is in an amount of 41.5 mg/mL.

4. The pharmaceutical formulation of claim **1**, wherein said solution further comprises a citrate buffer.

5. The pharmaceutical formulation of claim **4**, wherein said citrate buffer is at a concentration of 20 millimolar.

6. The pharmaceutical formulation of claim **1**, wherein said solution is buffered at a pH of 5.0 ±0.5.

7. The pharmaceutical formulation of claim **1**, wherein said EDTA is in an amount of 0.5 mg/mL, wherein said mannitol is in an amount of 41.5 mg/mL, wherein said solution further comprises a citrate buffer at a concentration of 20 millimolar, and wherein said solution is buffered at a pH of 5.0 ±0.5.

8. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 18 months when stored at room temperature.

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